SUMMARY

Autologous bone marrow transplantation (ABMT) may be a useful way of permitting an increased intensity of treatment of patients with acute myeloid leukemia (AML), potentially curing a higher proportion of patients. However, the marrow harvested in apparent clinical remission may contain residual malignant cells which contribute to disease recurrence. We have been using the Neo^R containing retrovirus vectors LNL6 and G1N to mark of one-third of all harvested autologous marrow to trace the origin of relapse.

To date, 11 patients with AML have received gene marked marrow. Marking did not delay engraftment compared to historical controls. Two patients have subsequently relapsed. In both, a proportion of the relapsed cells contained the marker gene. Since this study shows that "remission" marrow may indeed be contaminated with malignant cells that can contribute to relapse, we now propose to incorporate marrow purging into the protocol, in an attempt to remove these cells.

We intend to use both the LNL6 and G1N vectors in every patient who will receive an ABMT. Each vector will be used to mark one-third of the marrow. The remaining third will be cryopreserved unmanipulated as a back up. Each of the marked portions of marrow will be randomized to be purged either with 4-hydroxyperoxycyclophosphamide or with interleukin-2. After purging the marrows will be reinfused. If the patients relapse, we will discover if the marker is present in the relapse cells, and if it is, with which purging technique the relapse is associated. In this study we propose to treat 35 patients.